Errata #2

to the

BRIEFING BOOK

ONCOLOGY DRUGS
ADVISORY COMMITTEE MEETING

February 10, 2010

NDA 22-374
OMAPRO™
(omacetaxine mepesuccinate)

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Page 51, Table 11
Corrected typographical error: Vomiting, CML Safety Cohort, Grade ≥ 3 from "12 (9.2%)" to "0".

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Table 11. Common Adverse Reactions Reported in Patients in the Full Safety Database and CML Safety Cohort, Regardless of Relationship to Study Drug

	Full Safety Database n = 212		CML Safety Cohort n = 131	
Preferred Term	**All grades n (%)**	**Grade ≥ 3 n (%)**	**All grades n (%)**	**Grade ≥ 3 n (%)**
Number of patients with at least one adverse event	206 (97.2%)	184 (86.7%)	129 (98.5%)	116 (88.5%)
Thrombocytopenia	108 (50.9%)	95 (44.8%)	79 (60.3%)	72 (55.0%)
Anemia	93 (43.9%)	55 (25.9%)	64 (48.9%)	45 (34.4%)
Diarrhea	84 (39.6%)	10 (4.7%)	56 (42.7%)	7 (5.3%)
Neutropenia	65 (30.7%)	58 (27.4%)	50 (38.2%)	46 (35.1%)
Nausea	60 (28.3%)	5 (2.4%)	36 (27.5%)	2 (1.5%)
Fatigue	57 (26.9%)	12 (5.7%)	41 (31.3%)	9 (6.9%)
Pyrexia	56 (26.4%)	9 (4.2%)	39 (29.8%)	3 (2.3%)
Asthenia	42 (19.8%)	4 (1.9%)	28 (21.4%)	2 (1.5%)
Leukopenia	34 (16.0%)	27 (12.7%)	18 (13.7%)	16 (12.2%)
Vomiting	33 (15.6%)	3 (1.4%)	17 (13.0%)	0
Headache	32 (15.1%)	5 (2.4%)	25 (19.1%)	2 (1.5%)
Cough	28 (13.2%)	2 (0.9%)	22 (16.8%)	1 (0.8%)
Injection site erythema	27 (12.7%)	0	21 (16.0%)	0
Anorexia	27 (12.7%)	2 (0.9%)	19 (14.5%)	2 (1.5%)
Arthalgia	27 (12.7%)	3 (1.4%)	22 (16.8%)	1 (0.8%)
Constipation	27 (12.7%)	7 (3.3%)	20 (15.3%)	0
Epistaxis	24 (11.3%)	1 (0.5%)	19 (14.5%)	1 (0.8%)
Edema peripheral	23 (10.8%)	2 (0.9%)	21 (16.0%)	1 (0.8%)
Febrile neutropenia	22 (10.4%)	20 (9.4%)	18 (13.7%)	16 (12.2%)
Pain in extremity	22 (10.4%)	4 (1.9%)	18 (13.7%)	3 (2.3%)
Abdominal pain	21 (9.9%)	1 (0.5%)	15 (11.5%)	0
Disease progression	18 (8.5%)	15 (7.1%)	16 (12.2%)	13 (9.9%)
Alopecia	16 (7.5%)	0	14 (10.7%)	0
Lymphopenia	15 (7.1%)	14 (6.6%)	15 (11.5%)	14 (10.7%)

Full Safety Database = Combined safety dataset of 212 patients from six studies

CML Safety Cohort = Combined safety dataset of 131 patients from studies CML-202 and CML-203